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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,098	07/12/2001	Tugrul T. Kararli	Pharmacia Case 3351.2	1335

26303 7590 03/18/2003

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EXAMINER

FAY, ZOHREH A

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 03/18/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/904,098

Applicant(s)

KARARLI ET AL.

Examiner

Zohreh Fay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5-9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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Claims 1-27 are presented for examination.

has been an inadvertent mistake in including claim 28 in Group I of the restriction requirement.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 and 23-27 are rejected under 35 U.S.C. 102 (b) as being anticipated by WO 00/25771. The WO patent teaches the use of the claimed COX-2 inhibitors in an ophthalmic formulation for the treatment of inflammatory conditions of the eye. See page 4, lines 9 and lines 26-33.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patent ability shall not be negated by the manner in which the invention was made.

Claims 8-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO Patent 00/25771 in view of Davis et al. (U.S. Patent 5,192,535) and Mazuel et al. (U.S. Patent 4,861,760).

The WO Patent teaches the use of COX-2 inhibitors in an ophthalmic formulation for the treatment of the inflammatory conditions of the eye. See Page 4, lines 9 and lines 26-33. The above reference also teaches the use of cyclodextrin to increase stability and the use of polymers to increase viscosity. See Page 5, lines 3-7. Davis et

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al. teach the addition of the crosslinked polymers, such as Polycarbophil to ophthalmic formulation as old and well known. See column 12, example II. Mazuel et al. teach the use of polysaccharides in combination with non-steroidal anti-inflammatory agents in ophthalmic formulation as old and well known. See column 2, lines 16-25 and column 5, lines 59-65. The primary reference differs from the claimed invention in the presence of the specific concentrations, particle size and specific polymers. It would have been obvious to a person skilled in the art to add the claimed polymers to the claimed composition, considering that Davis et al. teach the use of polycarbophil in ophthalmic compositions as old, and Mazuel et al. teach the use of polysaccharides in an ophthalmic formulation as old.

One skilled in the art would have been motivated to combine the teachings of the above references, since one relates to the use of the claimed COX-2 inhibitors in an ophthalmic formulation in combination with cyclodextrin and polymers for the treatment of inflammatory conditions of the eye, and the other two relate to the use of the claimed specific polymers in ophthalmic formulation as old. The substitution of one ophthalmic well known polymer for another is considered to be within the skill of the art in the absence of evidence to the contrary. The determinations of optimum proportions or amounts is considered to be within the skill of artisan in the absence to evidence to the contrary. Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 8-22 are rejected under 35 U.S.C. 103.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Fay whose telephone number is (703) 308-4604. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Z.F
March 17, 2003

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1200

